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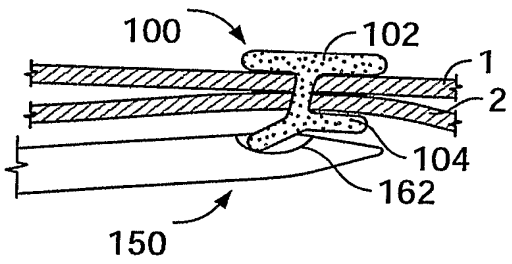
(54) Title: SURGICAL FASTENING SYSTEM



(57) Abstract: Devices and systems related to surgical fasteners and more specifically to surgical fasteners suitable for use in both open procedures, and minimally or less invasive procedures where the operative site is remote from the surgeon.

SURGICAL FASTENING SYSTEM

FIELD OF THE INVENTION

[0001] The present invention relates to surgical fasteners and more specifically to surgical fasteners suitable for use in both open procedures, and minimally or less invasive procedures where the operative or surgical site is not directly accessible by the surgeon.

BACKGROUND OF THE INVENTION

[0002] Surgical fasteners are known to be an alternative to traditional suturing techniques, for procedures involving tissue closure, connection, or repair. One undesirable aspect of manual suturing is that the suturing process adds time to the overall surgical process. Moreover, manual suturing often requires that the operative area is readily accessible so that the medical practitioner can manipulate the suture and associated needle through both sides of the tissue, connection or repair site. Presently, surgical fasteners are known to provide a means to close an open surgical incision or wound, hold together pieces of soft tissue, attach devices to tissue, or repair torn tissue in orthopedic/musculoskeletal applications. Such surgical fasteners are often used where there is adequate access to the operative area, or for invasive, open procedures.

[0003] Due to the inherent risks and complexities of invasive surgical procedures, there is an increasing need for the ability to perform surgical procedures in a minimally invasive manner. In most cases, the recuperative time and lowered expense of a minimally invasive procedure makes it a far more desirable option to an

alternative comparable invasive/open surgical procedure. The use of surgical fasteners in minimally invasive procedures may be desirable to increase the speed and efficiency of the procedure. Such fasteners may also open the possibility of performing a minimally invasive procedure for what was previously limited to an open surgical procedure.

[0004] In addition, suturing techniques requires considerable skill and dexterity especially when tying knots in the suture or otherwise manipulating the suture. The ability of a medical practitioner to manipulate a suture as well as knot the ends of the suture are further complicated when the site is not directly accessible to the practitioner. In such cases, even if the complexity of suturing does not prevent the procedure from being completed in a minimally invasive manner, the length of the procedure is likely to increase.

[0005] Conventional fasteners do not easily lend themselves for use in minimally invasive surgical procedure. As one example, the complexity of the known fastener-delivery devices requires devices with large profiles and limited flexibility further thereby limiting the potential for such devices to access remote locations. Conventional surgical fasteners, especially, "I-shaped" or "H-shaped" fasteners are unsuitable for remote procedures due to their complex deployment mechanisms and inability to navigate tortuous pathways using access devices commonly used for minimally invasive procedures (e.g., catheters, introducer devices, scope-type devices such as endoscopes, bronchoscopes, colonoscopies, etc.). Examples of such fasteners and devices are discussed in U.S. Patent Nos. 4,006,747 to Kronenthal et al., 4,235,238 to Ogiu et al., 4,669,473 to Richards et al., 5,941,439 to Kammerer et al,. 6,039,753 to Meislin, and U.S. Patent Publications US2003/0097148 to Valimaa et al, U.S. 2003/0187465 to Bailly et al. Each of the foregoing patents and/or patent applications is hereby incorporated in their entirety by reference.

SUMMARY OF THE INVENTION

[0006] The present invention includes a surgical fastener for deployment through a device (such as a needle, cannula, catheter, etc.), where the fastener comprises a first anchor member, a second anchor member, and a connecting portion separating the first and second anchor members, where at least the first anchor member and the second anchor member each are expandable from a first state to a second state where the second state is of a larger size than the first state, where the larger size may be achieved by an increase in displacement (e.g., volume, profile, configuration, etc.) of a portion of the fastener or the entire fastener. For example, as it assumes the second state, the anchor may change in shape or conform to a profile that is of a larger size than the profile of the first state. Alternatively, or in combination, the increase in volume may be achieved by relaxing a previous state of compression of the fastener portion. In the latter case, the fastener portion may comprise a resilient material that is compressible, and/or the fastener portion may be hollow, or have a cavity, such that the outer perimeter of the anchor portion may be folded into the cavity to assume the first state, or compress the cavity to conform to a smaller state.

[0007] The surgical fastener may also comprise a first means for anchoring the fastener, a second means for anchoring the fastener and a connecting portion separating the first and second means for anchoring. Where the means for anchoring may be any of the anchor portions described herein.

[0008] The invention also includes a surgical fastening system comprising, a tubular member having a proximal and distal end and a lumen extending therebetween, the tubular member being sufficiently flexible to navigate tortuous anatomical passages within a human body, a distal portion located at the distal end of the tubular member, the distal portion having a distal tip being configured to pierce tissue, the distal portion having a lumen extending between the tubular member

lumen and an opening in the distal portion, at least one surgical fastener slidably located entirely inside the tubular member lumen, where the surgical fastener comprises a first anchor member, a second anchor member, and a connecting portion separating the first and second anchor members, and an advancing member slidably located within the tubular member lumen such that advancement causes a distal portion of the advancing member to advance the surgical fastener through the tubular member. The system of the present invention may be directed to the desired site using a catheter-guidewire configuration, shaped catheter, a steerable catheter, a scope-type of device (e.g., such as endoscopes, gastroscope, colonoscope, bronchoscope, or any type of scope used to access sites within the body.)

[0009] It should be noted that alternate variations of the present invention include fastening system of the present invention used with conventional fasteners and/or fasteners of as described herein.

[0010] The present invention is useful in many surgical procedures requiring fastening systems, including but not limited to, procedures for fastening or repairing tissue or attachment of implant materials to tissue. The present invention is suitable for, but not limited to, use in the heart, stomach, gastro-intestinal tract, etc. While the faster and fastening system may be used in open procedures, the devices and systems may also be used in minimally invasive procedures where the operative site is remotely accessed using minimally invasive techniques including catheterization and/or endoscopic or similar means.

[0011] The inventive devices are especially suited for advancement via a minimally invasive technique by providing features which improve the ability of the surgeon to deploy the fastener with accuracy and effectuate a proper seal with the fastener. The minimally invasive technique also may allow for visual inspection of the placement of the anchor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIGS. 1A-1B, illustrate a side view of a basic variation of a fastener of the present invention.

[0013] FIGS. 2A-2H illustrate additional examples of various fasteners.

[0014] FIGS. 3A-3B illustrate a variation of a fastener having a single diameter (or similar cross-sectional measurement) prior to deployment.

[0015] FIG. 3C illustrates a variation of a fastener having an insert.

[0016] FIG. 4A-4C illustrate an example of a fastener system deploying a fastener.

[0017] FIGS. 5A-5B illustrate another variation of a fastener system.

[0018] FIG. 6A illustrates a deployed fastener having elastic properties.

[0019] FIG. 7A-7C illustrate variations of fastening systems of the present invention.

[0020] FIGS. 8A-8F illustrate additional features of fastening systems of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0021] The following illustrations are provided as variations of the present invention. It should be understood that there are many combinations of the present invention and that figures illustrating all variations of the invention would be numerous. Therefore, the invention is intended to include combinations of aspects and features of the illustrated embodiments, or combinations of the specific embodiments themselves.

[0022] FIGS. 1A-1B, illustrate a side view of a basic variation of the inventive fastener **100**. As seen in FIG. 1A, the fastener **100** includes a first anchor member **102** and a second anchor member **104** and a connecting portion **106** separating the two anchor members **102 104**. The "I-type" fastener shape illustrated

in FIGS. 1A-1B is merely for illustrative purposes. Naturally, the anchor portions **102 104** may have a variety of shapes, cross-sections, and configuration as discussed herein. However, the anchor portions **102 104** will generally have a shape that allows for retention of a medium (for example, torn/damaged tissue, two or more discrete pieces of tissues, one or more implants to tissue, a combination thereof, etc.) between the anchor portions **102 104** upon deployment of the anchor 100. Portion(s) of the fastener **100** will be operable between a first and second state where in the second state, a portion or portions of the fastener **100** will be of a larger size and/or profile than the first state. In the variation shown in FIG. 1B, the fastener **100** anchors **102 104** are configured so that they expand from the first state, shown in FIG. 1A, to a larger second state.

[0023] In use, the fastener **100** may be delivered to the operative site when the portions of the fastener **100** are in the first state. Upon deployment, selected portions of the fastener **100** assume the larger second state. This configuration allows for delivery of the fastener **100** through an opening in the medium where the opening is smaller than a diameter (or other similar dimension) of the fastener **100** portions after deployment. In some variations of the invention, construction of the fastener **100** allows only a portion (e.g., a single anchor, both anchors, the connecting portion, or a combination thereof) to expand into the second state. In other variations, the entire fastener **100** may be constructed to assume the second state upon deployment. It is contemplated, that the various portions of the fastener **100** may expand differently as required for the particular application (e.g., one or more portions expand at a different rate, a different size, etc.)

[0024] Expansion of the fastener **100** from the first to the second state may be accomplished a variety of ways. For example, the fastener **100** may be constructed of a shape or material that allows compression of the fastener portion, either by application of a compressive force or application of a vacuum, etc. Alternatively, or

in combination, the fastener **100** may include a material that swells or expands given the addition of a fluid (e.g., natural body fluids or fluids introduced during the surgical procedure.)

[0025] Examples of these materials include biodegradeable and non-biodegradeable polymers, elastomers, shape-memory alloys, other alloys, etc.) For example, carbonate copolymer, polyether ester copolymer, albumin, gelatin, starch, cellulose, dextrans, polysaccharides, fibrinogen, poly (D,L lactide), poly (D,L-lactide-co-glycolide), poly (glycolide), poly (hydroxybutyrate), poly (alkylcarbonate) and poly (orthoesters), EVA copolymers, silicone rubber and poly (methylmethacrylate). Particularly preferred polymeric carriers include poly (ethylene-vinyl acetate), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol, PET, PETE, and blends thereof.

[0026] In any case, the second state of the fastener comprises a larger profile or configuration as compared to the first state. As stated above, this permits securing of the anchoring portions **102 104** about the medium and/or securing of the connecting portion **106** within the medium. Another advantage of the invention is that the opening in the medium created during deployment of the fastener **100** may be smaller than would otherwise be possible if the fastener did not expand into the second state upon or after deployment.

[0027] It is also contemplated that the fastener may incorporate a variety of additives, coatings, adjuncts, etc. For example, the fastener (or only portions of the fastener) may include a lubricious coating to improve advancement of the fastener in the delivery system. The fastener may include non-proliferative drugs, thrombogenic additives, non-thrombogenic additives, non-inflammatory medicines, additives to

induce fibrosis for wound closure, anti-platelet, anti-coagulent, growth factors, gene-transductors, cell matrix, glue, cement, protein, hydrophilic, hydrophobic, lipidphillic, lipidphobic, or combinations where appropriate.

[0028] Figures 2A-2H illustrate examples of various fasteners **100** of the present invention. It should be understood that the fasteners **100** of the present invention may have a number of configurations as required for the specific application. These figures are intended to illustrate some possible variations of the invention. As noted herein, where possible, combinations of features of various embodiments and the embodiments themselves are within the scope of the invention. FIG. 2A illustrates a fastener **100** similar to that shown in FIGS. 1A-1B. FIG. It is contemplated that for the basic configuration of the fastener **100** illustrated in FIG. 2A (and where appropriate for other variations) the anchor portion **102 104** or the connecting portion **106**, individually or collectively, may have cross sections of a variety of shapes, including but not limited to circular, rectangular, square, star-shaped, etc.

[0029] FIG. 2B illustrates a variation of the fastener **100** where the anchor portions **102 104** have a spherical shape. In this variation, the anchor portions **102 104** are illustrated as having a cavity **108**. The cavity **108** may assist in reducing the size of the anchor portions **102 104** into the first state. Moreover, as described herein, the cavity **108** (as well as other portions of the fastener **100**) may serve as a reservoir for various medications, drugs, etc. Furthermore, variations of fasteners of the present invention may be non-porous if the particular application requires (e.g., where prevention of tissue in-growth is required. Alternatively, variations of the fastener may be porous. Furthermore, the fastener may be selected such that certain portions of the fastener are porous while others are non-porous (e.g., porous anchor members combined with a non-porous connecting member, non-porous anchors with a porous

connecting member, etc.) In such variations, porous materials may be selected for construction of the anchor or non-porous materials may be altered to contain pores.

[0030] FIG. 2C illustrates another variation of the fastener **100** in which the anchor portions **102 104** comprise cross-shaped members. FIG. 2D illustrates a fastener **100** having anchor portions **102 104** that are planar-disc-shaped. In such a configuration, the increased surface area of the anchor portions **102 104** may provide better contact between the fastener **100** and the medium to allow for tissue in-growth or for delivery of a therapeutic substance carried by the fastener **100**. FIG. 2E illustrates a variation of a fastener **100** of the present invention where the first anchor portion **102** and the second anchor portion **104** comprise different shapes. It should be noted that variations of the invention include fasteners **100** having combinations of anchor portions as illustrated herein or variations thereof.

[0031] FIG. 2F illustrates a variation of a fastener **100** of the present invention where the first anchor portion **102** and the second anchor portion **104** extend in different directions.

[0032] FIG. 2G illustrates a variation of the fastener **100** of the present invention where the anchor portions **102** and **104** comprise "pig-tail" type fasteners. In this variation, the anchor portions **102** and **104** the coils of the pig-tail may separate to capture tissue therebetween. Alternatively, the opposing anchor portions **102** and **104** may be used to capture the tissue. During placement of the fastener **100** the pig-tail anchors may be straightened in the device for delivery. Alternatively, the coils may be compressed in a radial dimension to expand upon deployment from the delivery system. A variation of a pig-tail fastener may include a helical shaped fastener or fastener with helical anchor portions.

[0033] FIG. 2H illustrates another variation of the invention where a fastener **100** includes protrusions **112**. The protrusions **112** may assist in retaining the anchors and or fastener in the deployment site. Alternatively, or in combination, the

protrusions **112** may comprise bio-active substances as described herein. Although the figure illustrates the protrusions as on the anchor portions only, the invention includes fasteners **100** having protrusions **112** on the connecting portion **106** as well. Alternatively, the protrusions **112** may be located only on the connecting portion **106**.

[0034] The invention also contemplates that the anchor portions described herein may be configured/suited for attachment of external devices/implants/objects/etc. For example, one possible use of the inventive fastener is placing the fastener in the wall of an organ, then attaching an implant to the organ's wall by attaching the implant to the anchor portions of the fastener.

[0035] FIGS. 3A-3B illustrate another variation of a fastener **100** of the present invention. In this variation, as shown in FIG. 3A, in the pre-deployment or first state, the anchor portions **102 104** have substantially the same cross sectional measurement as the connecting portion **106**. As illustrated in FIG. 3B, when the anchor portions **102 104** assume the second state, they expand to a greater size than the connecting portion **106**. As discussed herein, the anchor portions **102 104** may be constructed from a material similar to that of the connecting portion **106** but having different additives or structure to allow for expansion into the second state. Alternatively, portions of the fastener **100** may be formed from different materials and joined, or molded together to form the composite fastener.

[0036] FIG. 3C illustrates another variation of a fastener **100** of the present invention. In this variation, the fastener **100** includes an insert **110**. The insert **110** may comprise a bioabsorbable material which dissolves/ is absorbed by the body at a slower rate than the remainder of the fastener **100**. Alternatively, the insert **110** may be a nonbiodegradeable/non-bioabsorable material such that as tissue replaces the absorbable fastener material, the insert remains to provide long term retention of tissue. Moreover, the insert **110** may comprise a metallic material to provide a radiopaque marker for placement, or for subsequent location of the fastening site.

Such a combination may be used with absorbable and non-absorbable fasteners. Although the insert **110** illustrated in FIG. 3C comprises end portions having a larger dimension than the center portion, the invention is not limited as such.

[0037] FIG. 4A-4C illustrate a basic example of a system **150** which deploys fasteners **100** of the present invention. As shown in FIG. 4A, the system **150** includes a tubular member **152** that is sufficiently flexible so that it may navigate tortuous passages to access the surgical site yet it will have sufficient column strength so that it may penetrate tissue to deploy the fastener **100**. As such, variations of the tubular member **152** may be reinforced to minimize kinking of the tubular member as it navigates toward the surgical site. In this variation, the tubular member **152** retains a fastener **100** in a lumen **154** that extends between a proximal and distal end of the tubular member **152**. The fastener **100** is slidably located inside the tubular member **152** and may be advanced using an advancing member **156** that is also slidably located within the tubular member lumen **154**.

[0038] It is contemplated that various methods known in the field may be employed to advance/retract the advancing member. For example, the advancing member may simply push the fastener using a linear or rotary type drive system. Alternatively, the advancing member may be an auger type system that advances the fastener with the assistance of rotatable vanes within the tubular member. A pneumatic, hydraulic, or fluid filled actuation may also be used to advance/retract the advancing member. The advancing member **156** may be a guidewire or other similar type device that is able to deploy the fastener **100** at the operative site. Although not illustrated, the fastener **100** may be removably attached to the advancing member **156** to improve accuracy in deployment of the fastener **100**. In some variations of the invention, the fastener **100** is configured relative to the lumen **154** so that friction retains the fastener **100** within the lumen **154** until deployment of the fastener **100**. In such cases, the wall surface and/or diameter of the lumen **154** may be selected to

increase the sliding resistance of the fastener **100**. In any case, the system will be configured so that upon deployment of the first anchor the fastener **100** will release from the device rather than pulling out of the tissue.

[0039] The system **150** also includes a distal portion **158** located at the distal end of the system **150**. The distal portion **158** has a distal tip **160** configured to pierce tissue and has an opening **162** through which the fastener **100** exits the device. In some variations of the invention, the distal tip **160** is configured to prevent "coring" of the tissue to minimize the size of any opening created during deployment of the fastener. Instead, the tip **160** configuration has a sharpened area and a taper proximal to the sharpened area so that the tip **160** makes a small puncture and then dilates the opening in the tissue.

[0040] FIG. 4B illustrates the system **150** of FIG. 4A after the distal portion **158** advances through two layers of tissue **1** and **2** and one anchor portion **102** exits from the system **150**. As discussed herein, the fastener **100** may expand upon exiting the system **150** via being released from the constraint of the system **150**. Alternatively, or in combination, fluids (not shown) may cause the fastener **100** to increase in size. Such fluids may be introduced during the procedure or may be naturally occurring at the operative site. Therefore, the fastener **100** may expands to a size greater than the opening in tissue that is created by the fastening system **150**. Next, the distal portion **158** and tubular member **152** are retracted through the tissue **1**. Once retracted, the system **150** deploys the second anchor portion (not illustrated) thereby retaining the tissues **1** between the anchor portions **102 104**.

[0041] FIG. 4C illustrates the system **150** of FIGS. 4A and 4B after the distal portion **158** is withdrawn through the tissue **1** sufficiently enough so that the opening **162** is on the near side of the tissue **1**. Once in the appropriate position, the device **150** deploys the remaining anchor portion **104**. It should be understood that the system illustrated in FIGS. 4A-4C is depicted to show a basic variation of the

invention. It is contemplated that the invention includes variations configured to first deploy an anchor portion on a near side of the tissue (e.g., prior to insertion of the distal tip into the tissue), then advance the distal tip into the tissue to deploy the remaining anchor portion on the far side of the tissue.

[0042] Although the fastener of the present invention may be delivered through any tubular device such as a cannula, a catheter, polymeric tubing, etc., the fastener may be part of a fastening system that permits deployment of the fastener in remote parts of the body through a variety of minimally invasive procedures. In such cases, the system may include a steerable catheter, or the system may be guided to the site via a separate catheter, a separate steerable catheter, a endoscope-type device, pre-shaped catheter, etc.

[0043] FIGS. 5A-5B illustrate another variation of a system **150** of the present invention. In this variation, the opening **162** is located at a distal end of the device rather than in a side-wall of the distal portion. In such a variation, the fastener **100** may be located immediately adjacent the opening **162** to prevent the coring of tissue as the distal tip **160** advances through tissue. FIG. 5B illustrates a sectional view taken along the line 5B-5B of FIG. 5A. As illustrated, the system **150** may include a lumen that is appropriately shaped to orient the anchor and central portions of the fastener **100**. For example, the lumen may be extruded to form a channel for the central portion. Additionally, as shown in FIG. 5B, the system may include a multi-lumen design to allow for fluid delivery ports **164** if required.

[0044] As discussed herein, upon deployment of the fastener **100** from the system **150**, the fastener **100** portions shall increase in size from the first state to a second state where the larger size may be achieved by an increase in volume and/or profile a portion of the fastener or the entire fastener. The invention contemplates that the fastening delivery system **150** may be used to constrain the fastener **100** into the first state, via a compression mechanism. Alternatively, or in combination, the

fastener **100** or portions of the fastener may be configured to increase in size given the application of a fluid. The fluid may comprise naturally occurring bodily fluid or fluid delivered by the fastening system or even fluid delivered via a separate device.

[0045] As discussed above, one of the functions of the inventive tissue fastener is to retain two pieces of tissue together, retain an implant to the tissue, or close an opening in tissue. The feature of the inventive fastener **100** relating to expansion of the anchor portions **102 104** permits placement of the fastener **100** using an opening in the tissue that is smaller would otherwise be required. Moreover, fasteners of the present invention may also be configured such that the central portion **106** expands into a second state as well. In such variations, expansion of the center portion may allow for expedited healing of the opening in tissue, or for closure and sealing of the opening in the tissue. In additional variations of the invention, the central portion **106** may be configured from a material that allows stretching of the center portion **106** during deployment. As shown in FIGS. 6A, such a fastener **100** having elastic properties allows for an increased compressive force on the medium being retained between the fastener. An additional benefit of such an elastic fastener is that the length of the fastener **100** (e.g., as measured in a direction along the central portion) can accommodate a greater range of tissue and/or material thicknesses.

[0046] FIG. 7A illustrates a variation of a fastening system **150** of the present invention. Although the system **150** depicts a single fastener **100** located within the device, it is contemplated that the system **150** may comprise a number of fasteners **100** to permit serial deployment during use of the system. As illustrated, the system **150** includes a flexible tubular member **152** extending between having proximal and distal ends and a lumen extending between the ends. The system **150** includes a distal portion **158** the distal end of the tubular member **152.** It is contemplated that the distal portion **158** may comprise a separate material or insert that is coupled to the tubular member **152.** Alternatively, the distal portion **158** may be formed from the

same material as the tubular member **152**. The distal portion **158** includes a distal tip **160** for penetrating tissue (and/or an implant, etc.). The distal portion **158** includes a lumen that is in fluid communication with a lumen of the tubular member **152**. The distal portion **158** also includes an opening **162** through which the fastener **100** deploys.

[0047] In the illustrated variation, the opening **162** is located in a side wall of the distal portion **158**. However, as discussed herein, the opening may be at the distal tip **160**. It is contemplated that the tubular member **152** will have sufficient column strength to allow for penetration of tissue via advancement of the system **150**. Accordingly, the tubular member **152** may be constructed of a material that provides sufficient flexibility and column strength. Alternatively, the tubular member **152** may include a reinforcing member **166**, such as a coil, braid, or fiber reinforcement. Furthermore, as discussed above, the system **150** includes an advancing member **156** that permits advancement and/or deployment of the fastene r **100**. To improve advancement and deployment of the fastener, the tubular member and/or advancing member may be selected from materials that minimize the friction between the two members. Alternatively, or in combination, these items may include a lubricious coating to minimize friction. Although not illustrated, the system **150** may include an additional fluid delivery means, such as a fluid source where delivery of the fluid occurs via the lumen of the device, an additional fluid lumen, a separate catheter-type device for delivery of the fluid, etc.

[0048] FIG. 7B illustrates an additional variation of a fastening system **150** of the present invention. In this variation, the fastener **100** is depicted as being partially ejected from the system **150**. As shown, the distal portion **158** may include one or more fluid delivery ports **170** in fluid communication with fluid delivery lumen(s) **164** of the tubular member **152**. FIG. 7C is a sectional view taken along the lines of 7C-7C of FIG. 7B. As shown, the tubular member **152** may include a channel **155** to

aid in maintaining an orientation of the fastener and/or assist in advancement of the fastener. FIG. 7C also illustrates fluid delivery lumens **164** of the tubular member **152**. It is understood that the system may include a single or multiple fluid delivery lumens(s).

[0049] FIGS. 8A-8F illustrate variations of the fastening **150** of the present invention having features that aid in dispensing fasteners. Figures 8A-8C illustrate delivery systems having gate members **168** of a valve-type configuration. For example, the gate member **168** of these variations may comprise a flexible valve having a slit, gap, or opening therein. The gate member will function to impede movement of a portion of a surgical fastener from the system. Accordingly, a portion of the gate member will interfere with a portion of the fastener during its advancement in the system or out of the system. Although the gate **168** is illustrated as being placed in the opening **162** of the distal portion **158**, the gate **168** may also be located within a lumen of the system. FIG. 8C illustrates a variation of the fastening system **150** of the present invention depicting a fastener **100** that is partially deployed from the system **150**.

[0050] FIGS. 8D-8E illustrate additional features of a fastening system **150** of the present invention. The fastener and other features of the system are omitted for the sake of clarity. In the variation of FIG. 8D, the system **150** includes a gate member **168** located on a rotatable insert **170** located within the tubular member **152**. The rotatable insert **170** may have the same or similar features of the tubular member **152** and tubular member lumen as described above. In use, rotation of the rotatable insert **170** causes the gate member **168** (which may be formed by an opening in the rotatable insert) to impinge upon a portion of the fastener (not shown) as the fastener exits from the system **150**. In some variations of the invention, application of an increased torque to the gate member **170** may permit severing or cutting of the a

fastener or a connection between adjacent fastener. For example, some variations of the invention include fasteners that have a severable connection.

[0051] FIG. 8E illustrates a variation of the fastening system **150** where a gate member **168** is located on a distal end of a slidable insert **172**. The effect of the slidable insert **172** may be similar to that of the rotatable insert described above where the operative mechanism is advancement and retraction of the slidable insert. The slidable insert **172** may move independently of any advancing member (not shown) to allow proper dispensing of a fastener.

[0052] FIG. 8F illustrates another variation of a fastening system of the present invention, in this variation the fastening system **150** may include an advancing member **156** that is coupled to a fastener **100** via a detachable joint **172**. The detachable joint **172** may comprise a low-melt temperature polymer that is bonded to both the fastener **100** and the advancing member **156**. In such a variation, the advancing member **156** will be configured to heat the joint (for example, via conductive, resistive, chemical, etc, means.) Alternatively, the detachable joint **172** may comprise an electrolytic joint. In such a case, the fastener may comprise a metallic frame **110** as described above. In use, the fastener **100** may be positioned, and upon confirmation of its placement, the detachable joint **172** is activated to release the fastener.

We Claim:

1. A surgical fastening system comprising:

a tubular member having a proximal and distal ends and a lumen extending therebetween,

a distal portion located at the distal end of the tubular member, the distal portion having a distal tip being configured to pierce tissue, the distal portion having a lumen extending between the tubular member lumen and an opening in the distal portion;

at least one surgical fastener slidably located inside the tubular member lumen, where the surgical fastener comprises a first anchor member, a second anchor member, and a connecting portion separating the first and second anchor members; and

an advancing member slidably located within the tubular member lumen such that advancement causes a distal portion of the advancing member to advance the surgical fastener through the tubular member.

2. The surgical fastening system of claim 1, where the tubular member is sufficiently flexible to navigate tortuous anatomical passages within a human body.

3. The surgical fastening system of claim 1, where the surgical fastener is located entirely within the tubular member lumen.

4. The surgical fastening system of claim 1, further comprising a gate member in fluid communication with the tubular member lumen or distal portion lumen, the gate member having a portion that impedes movement of at least one surgical fastener.

5. The surgical fastening system of claim 4, where the gate member comprises a flexible valve, where the valve increases resistance to the fastener during advancement of the fastener.

6. The surgical fastening system of claim 4, where the gate member is moveably located in the distal portion lumen such that it may at least partially occlude the opening.

7. The surgical fastening system of claim 1, where the connecting portion of the surgical fastener has a greater elasticity than either the first or second anchor member such that when tissue is placed between the anchor members, the connecting member is placed in a tensile state providing a compressive force against the tissue by the anchor members.

8. The surgical fastening system of claim 1, where the advancing member is releasably coupled to at least one surgical fasteners.

9. The surgical fastening system of claim 1, where the opening is at the distal tip.

10. The surgical fastening system of claim 1, where the opening is in a wall of the distal portion.

11. The surgical fastening system of claim 10, where the distal tip is inserted into the distal portion.

12. The surgical fastening system of claim 1, where the surgical fastener is an I shaped, H shaped, helical shaped and pig-tail shaped fastener.

13. The surgical fastening system of claim 12, where the fastener is resilient and assumes the I shape, H shape, helical, or pig-tail shape upon deployment from the tubular member.

14. The surgical fastening system of claim 1, where the at least one surgical fastener comprises a plurality of surgical fasteners.

15. The surgical fastening system of claim 14, where the plurality of surgical fasteners are each connected.

16. The surgical fastening system of claim 1, where the tubular member comprises a reinforcing member to increase an axial strength of the tubular member.

17. The surgical fastening system of claim 1, where at least the first anchor member and the second anchor member each are expandable from a first state to a second state where the second state is of a larger displacement than the first state.

18. The surgical fastening system of claim 17, where the second state is of a larger volume than the first state.

19. The surgical fastening system of claim 17, where the first anchor member and second anchor member are compressible upon application of a compressive force and assume the second state upon removal of the compressive force.

20. The surgical fastening system of claim 19, where the first anchor member and second anchor members are sized relative to the tubular member lumen so that the tubular member provides the compressive force upon insertion of the anchor members into the tubular member.

21. The surgical fastening system of claim 19, where connecting portion is also expandable from the first state to the second state where the second state is of a larger volume than the first state.

22. The surgical fastening system of claim 17, where at least the first and second anchor members comprise a material that expands upon contact with a fluid.

23. The surgical fastening system of claim 1, where the tubular member further comprises a further comprising a fluid delivery, and where the distal tip further comprises a port in fluid communication with the fluid delivery lumen.

24. The surgical fastening system of claim 1, where the connecting portion has a greater elasticity than either the first or second anchor member such that when tissue is placed between the anchor members, the connecting member is placed in a tensile state providing a compressive force against the tissue by the anchor members.

25. The surgical fastening system of claim 1, where the connecting portion has a cross sectional area less than a cross sectional area of either the first or second anchor member.

26. The surgical fastening system of claim 1, where the advancing member is detachably coupled to the fastener.

27. The surgical fastening system of claim 26, where the advancing member is detachably coupled to the fastener via a detachable joint.

28. The surgical fastening system of claim 27, where the detachable joint comprises an electrolytic joint.

29. The surgical fastening system of claim 27, where the detachable joint comprises a polymer.

30. A surgical fastener for deployment through a device, the fastener comprising:

a first anchor member;

a second anchor member;

a connecting portion separating the first and second anchor members; and

where at least the first anchor member and the second anchor member each are expandable from a first state to a second state where the second state is of a larger size than the first state.

31. The surgical fastener of claim 30, where the second state is of a larger volume than the first state.

32. The surgical fastener of claim 30, where the first anchor member and second anchor member assume the first state upon application of a vacuum to the anchor members.

33. The surgical fastener of claim 30, where the first anchor member and second anchor member are compressible upon application of a compressive force and assume the second state upon removal of the compressive force.

34. The surgical fastener of claim 33, where the first anchor member and second anchor members are sized relative to the device so that the device provides the compressive force upon insertion of the anchor members into the device.

35. The surgical fastener of claim 30, where connecting portion is also expandable from the first state to the second state where the second state is of a larger volume than the first state.

36. The surgical fastener of claim 30, where at least the first and second anchor members comprise a material that expands upon contact with a fluid.

37. The surgical fastener of claim 30, where at least a portion of the anchors or the connecting member members contain a hollow portion.

38. The surgical fastener of claim 30, where the connecting portion has a greater elasticity than either the first or second anchor member such that when tissue is placed between the anchor members, the connecting member is placed in a tensile state providing a compressive force against the tissue by the anchor members.

39. The surgical fastener of claim 30, where the connecting portion has a cross sectional area less than a cross sectional area of either the first or second anchor member.

40. The surgical fastener of claim 30, where the connecting portion has a lower modulus of elasticity than a modulus of elasticity of either the first or second anchor.

41. The surgical fastener of claim 30, where the connecting portion is formed from a polymer or co-polymer that is different from the remainder of the fastener.

42. The surgical fastener of claim 30, where the connecting portion and anchors are formed from a polymer or co-polymer.

43. The surgical fastener of claim 30, further comprising a bioactive substance.

44. The surgical fastener of claim 43, where the bioactive substance comprises non-proliferative drugs, thrombogenic additives, non-thrombogenic additives, non-inflammatory medicines, additives to induce fibrosis for wound closure, anti-platelet, anti-coagulent, growth factors, gene-transductors, cell matrix, glue, cement, protein, hydrophilic, hydrophobic, lipidphillic, lipidphobic, or combinations where appropriate.

45. The surgical fastener of claim 30, where the fastener is bioabsorbable.

46. The surgical fastener of claim 30, where the fastener comprises a shape selected from a group consisting of an I-type fastener, an H-type fastener, a pig-tail fastener, a helical fastener.

47. The surgical fastener of claim 30, where the fastener comprises a plurality of pores adapted to facilitate tissue ingrowth.

48. The surgical fastener of claim 30, where at least the first and second anchor member comprises a material selected from the group consisting of poly (ethylene-vinyl acetate), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol, PET, PETE, and blends thereof

49. The surgical fastener of claim 30, where the first anchor member comprises a shape selected from the group consisting of a bar, disc, sphere, cylinder, a helical and a pig-tail shape

50. The surgical fastener of claim 49, where the second anchor member comprises a shape selected from the group consisting of a bar, disc, sphere, a helical and cylinder.

51. The surgical fastener of claim 30, further comprising an insert within a fastener material forming the fastener.

52. The surgical fastener of claim 51, where the insert comprises a material different from the fastener material.

53. The surgical fastener of claim 51, where the insert comprises a non-biodegradeable material.

54. The surgical fastener of claim 51, where the insert comprises a metallic material.

55. The surgical fastener of claim 51, where the insert material degrades slower than the fastener material.

56. The surgical fastener of claim 51, where the insert material is radiopaque.

57. A surgical fastener for deployment through a device, the fastener comprising:
a first means for anchoring the fastener;
a second means for anchoring the fastener and;
a connecting portion separating the first and second means for anchoring.

58. The surgical fastener of claim 28, where at least the first and second means for anchoring comprise a material that expands upon contact with a fluid.

59. The surgical fastener of claim 28, where the connecting portion has a greater elasticity than either the first or second means for anchoring such that when tissue is placed between the means for anchoring, the connecting member is placed in a tensile state providing a compressive force against the tissue by the means for anchoring.

60. The surgical fastener of claim 28, where the connecting portion is formed from a polymer or co-polymer that is different from the remainder of the fastener.

61. The surgical fastener of claim 28, further comprising a bioactive substance.

62. The surgical fastener of claim 32, where the bioactive substance comprises non-proliferative drugs, thrombogenic additives, non-thrombogenic additives, non-

inflammatory medicines, additives to induce fibrosis for wound closure, anti-platelet, anti-coagulent, growth factors, gene-transductors, cell matrix, glue, cement, protein, hydrophilic, hydrophobic, lipidphillic, lipidphobic, or combinations where appropriate.

63. The surgical fastener of claim 28, where at least the first and second means for anchoring comprises a material selected from the group consisting of poly (ethylene-vinyl acetate), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol, PET, PETE, and blends thereof

64. The surgical fastener of claim 28, where the first and second means for anchoring comprises a shape selected from the group consisting of a bar, disc, sphere, cylinder, a helical and a pig-tail shape

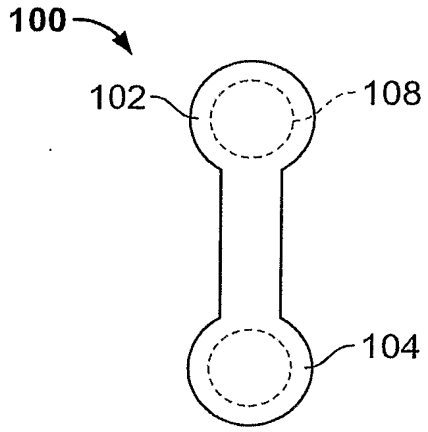


FIG. 2B

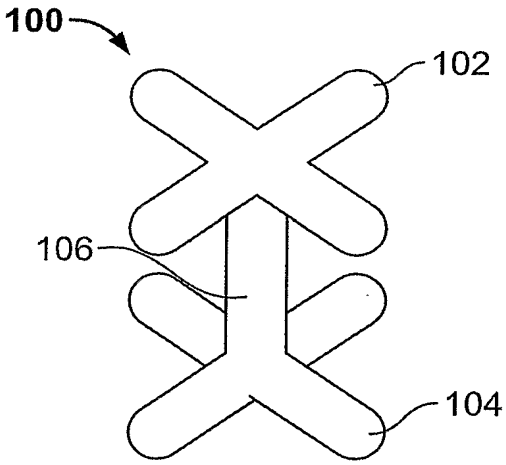


FIG. 2C

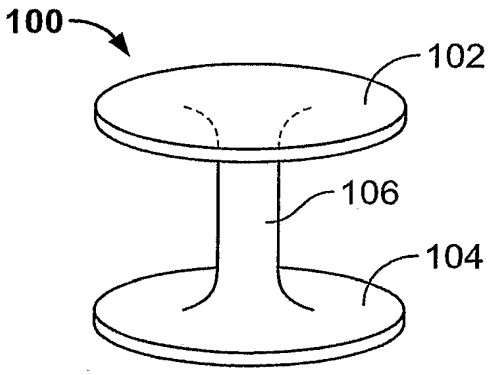


FIG. 2D

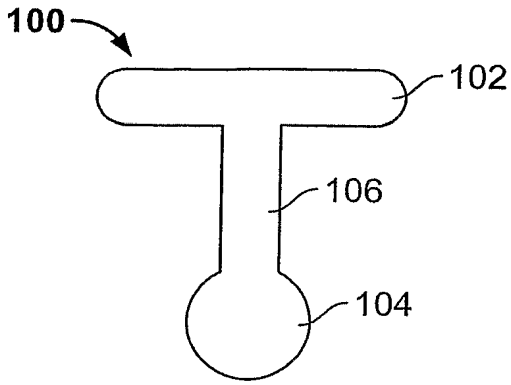


FIG. 2E

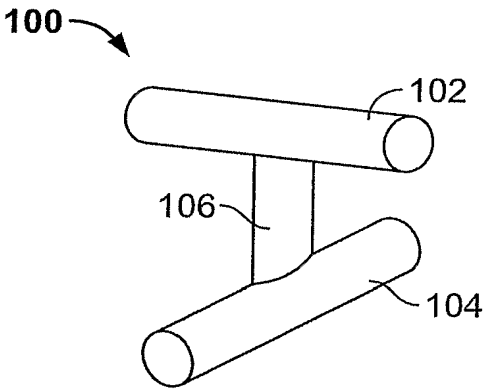


FIG. 2F

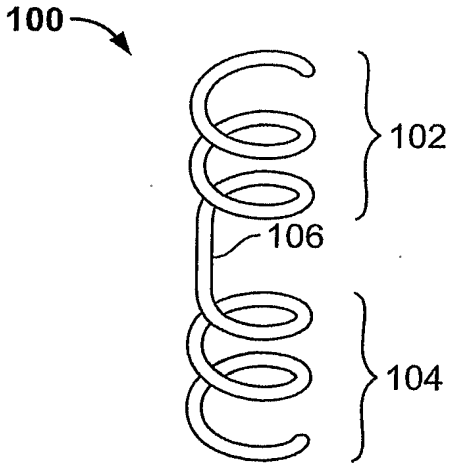


FIG. 2G

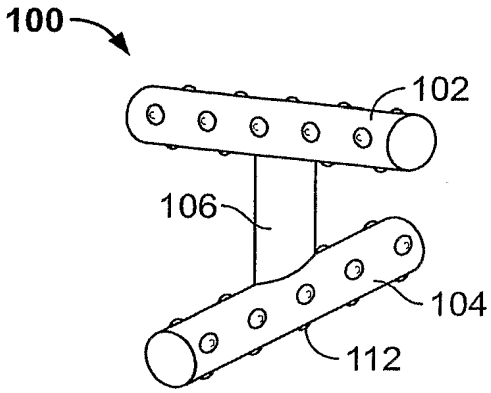


FIG. 2H

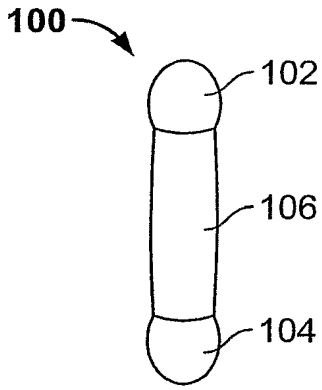


FIG. 3A

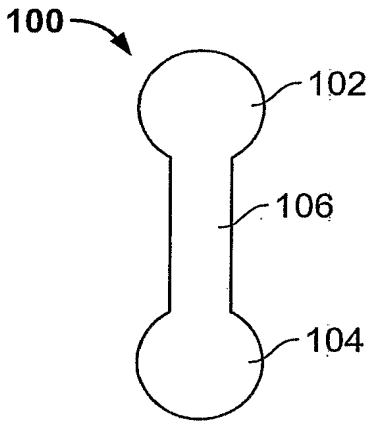


FIG. 3B

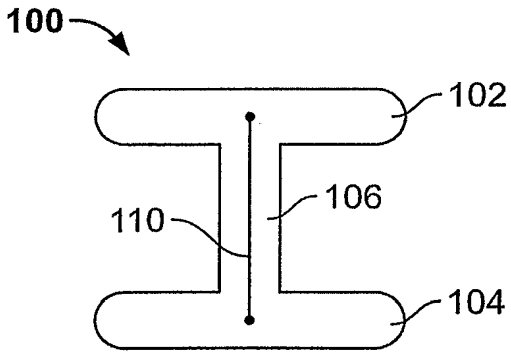


FIG. 3C

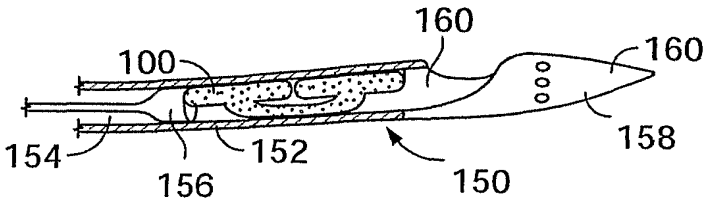


FIG. 4A

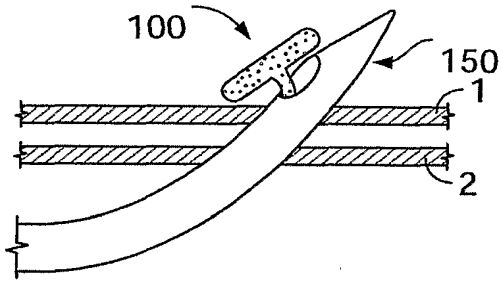


FIG. 4B

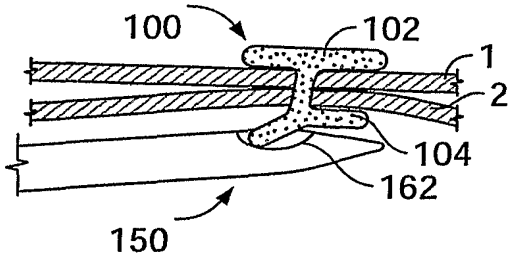


FIG. 4C

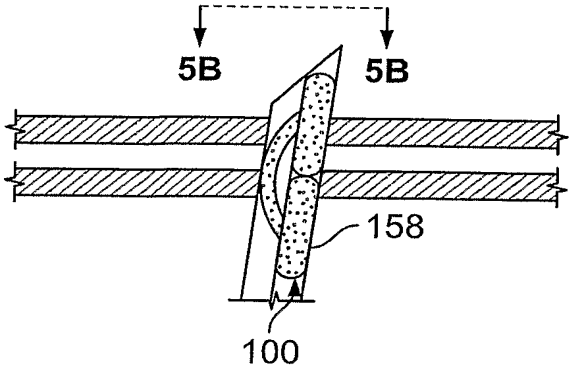


FIG. 5A

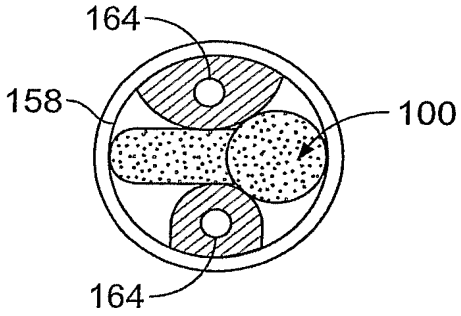


FIG. 5B

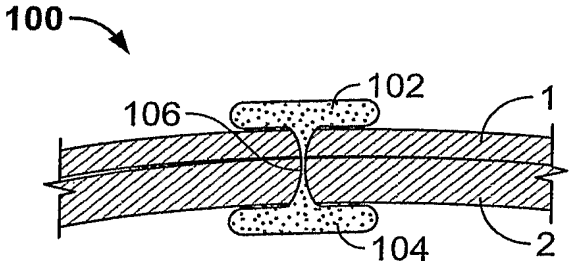


FIG. 6A

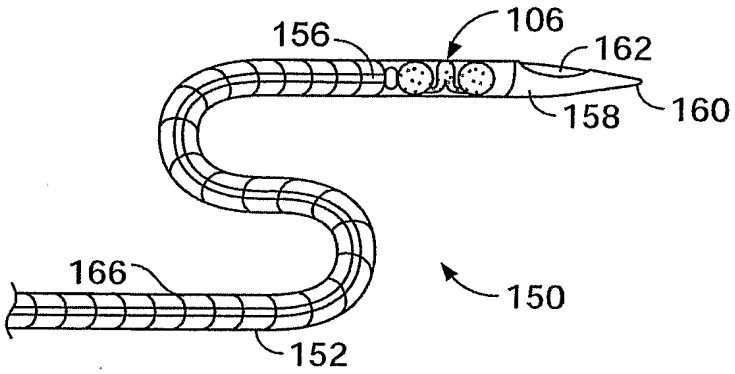


FIG. 7A

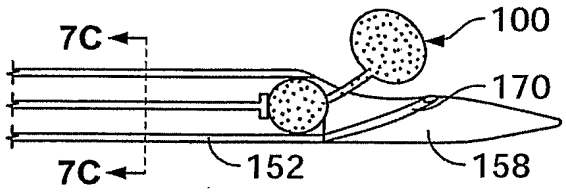


FIG. 7B

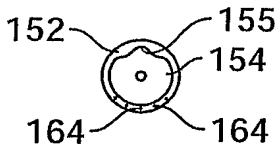


FIG. 7C

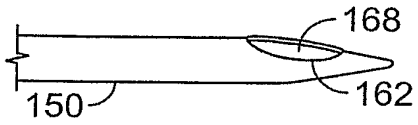


FIG. 8A

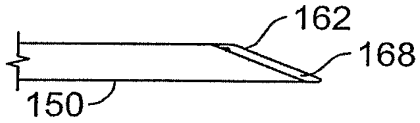


FIG. 8B

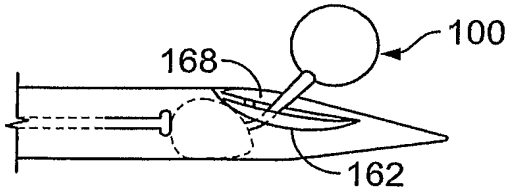


FIG. 8C

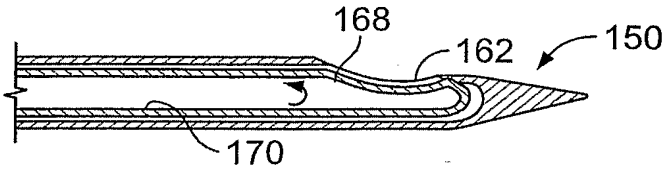


FIG. 8D

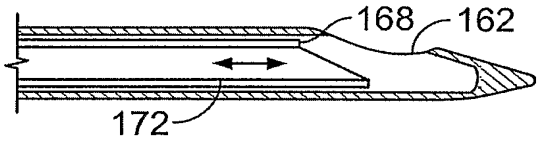


FIG. 8E

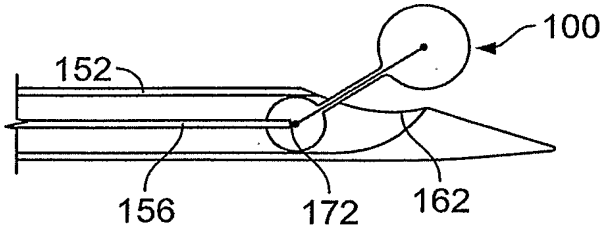


FIG. 8F